

MEDICARE PRESCRIPTION DRUG BENEFIT

2010 Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plan (PDP) Sponsors

2010 Contract Year

PUBLIC REPORTING BURDEN: According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0936. The time required to complete this information collection is estimated to average 37.25 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, C4-26-05, Baltimore, Maryland 21244-1850.

BACKGROUND:

The Medicare Modernization Act (MMA) provides employers and unions with a number of options for providing prescription drug coverage to their Medicare-eligible retirees. Under the MMA, those options include making special arrangements with Medicare Advantage Organizations (MAOs) and Section 1876 Cost Plans to purchase customized benefits, including drug benefits, for their retirees; purchasing benefits from sponsors of prescription drug-only plans (PDPs); and directly contracting with CMS to become Part D plan sponsors themselves. Each of these approaches involves the use of CMS waivers authorized under Sections 1857(i) or 1860D-22(b) of the Social Security Act (SSA). Under this authority, CMS may waive or modify requirements that “hinder the design of, the offering of, or the enrollment in” employer-sponsored group plans.

Which Applicants Should Complete This Application?

This application is to be used by employers or unions seeking to directly contract with CMS to become PDP Sponsors (“Direct Contract PDPs”) for their Medicare-eligible retirees. Please follow the application instructions below and submit the required material in support of your application to offer a Direct Contract PDP.

APPLICATION INSTRUCTIONS:

Applications must be submitted by 11:59 PM EST on February 26, 2009, by all employers or unions seeking to offer a Direct Contract PDP.

Which Application Materials Must Be Submitted and How Must These Materials Be Submitted?

All Direct Contract PDP Applicants must complete and submit the following:

- (1) The *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*. This portion of the application is submitted electronically through the Health Plan Management System (HPMS).
- (2) The 2010 Part D Financial Solvency & Capital Adequacy Documentation for Direct Contract PDP Sponsor Applicants (Appendix I of this application). This portion of the application is submitted electronically through HPMS as a supporting documentation upload to the Licensure and Solvency section of the Part D supporting file section. Applicants should not complete the Appendix for Financial Solvency in the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*.
- (3) The 2010 Direct Contract PDP Attestations. This portion of the application is submitted electronically through HPMS. A copy of these attestations is included with this application (Appendix II).
- (4) The 2010 Request for Additional Waiver/Modification of Requirements (Optional) (Appendix III of this application). This portion of the application is submitted electronically through HPMS as supporting documentation upload to the Attestation Waiver Request section of the Part D supporting file section. This submission is optional and should only be submitted if the Direct Contract PDP applicant is seeking new waivers or modifications of CMS requirements.

All of the above enumerated submissions will comprise a completed application for new Direct Contract PDP Sponsors. Failure to complete and submit item numbers 1 through 3 above will result in a denial of the Direct Contract PDP application (item number 4 is optional as noted above).

Using HPMS to Submit Application Materials

In order to submit the electronic portions of this application through HPMS please log on to HPMS and follow the instructions. To complete these application materials, please access the following link in HPMS:

Contract Management > Basic Contract Management > Select Contract Number > Online Applications

PDP EGWP SERVICE AREA AND PHARMACY ACCESS REQUIREMENTS:

New Direct Contract PDP Applicants will be able to enter their service areas directly into HPMS during the application process.

In general, Part D plans can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived these requirements for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more PDP regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PDP Applicants must set their service areas to include all areas where retirees may reside during the plan year (**no mid-year service area expansions will be permitted**).

Direct Contract PDP Applicants will be required to submit retail and other pharmacy access information for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

Appendix I

Part D Financial Solvency & Capital Adequacy Documentation For Direct Contract PDP Sponsor Applicants

Background and Instructions:

A PDP Sponsor generally must be licensed by at least one state as a risk-bearing entity (42 CFR 423.401(a)(1)). CMS has waived the requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors are not required to be licensed, but must meet CMS Part D financial solvency and capital adequacy requirements. Each Direct Contract PDP Sponsor Applicant must demonstrate that it meets the requirements set forth in this Appendix and provide all required information set forth below. CMS may in its discretion approve, on a case-by-case basis, waivers of such requirements upon a demonstration from the Direct Contract PDP Sponsor Applicant that its fiscal soundness is commensurate with its financial risk and that through other means the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS will require that the employer's/union's contracts and sub-contracts provide beneficiary hold harmless provisions.

The information required in this Appendix must be submitted electronically through HPMS as a supporting documentation upload to the Licensure and Solvency section of the Part D supporting file section in accordance with the above instructions contained in this application.

I. EMPLOYER/UNION ORGANIZATIONAL INFORMATION

A. Complete the information in the table below.

IDENTIFY YOUR ORGANIZATION BY PROVIDING THE FOLLOWING INFORMATION:	
Organization's Full Legal Name:	
Full Address of Your Organization's Headquarters (<i>Street, City, State, Zip</i>):	
Type of Entity (place a checkmark in <u>all</u> applicable boxes):	
<input type="checkbox"/> Employer <input type="checkbox"/> Fund established by one or more employers or labor organizations <input type="checkbox"/> Union <input type="checkbox"/> Government <input type="checkbox"/> Church Group <input type="checkbox"/> Publicly-Traded Corporation <input type="checkbox"/> Privately- Held Corporation <input type="checkbox"/> Other (list type) _____	
Name of Your Organization's Parent Organization, if any:	
Is Applicant subject to ERISA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Tax Status: <input type="checkbox"/> For Profit <input type="checkbox"/> Not-for-Profit
State in Which your Organization is Incorporated or Otherwise Organized to do Business:	

B. Summary Description

Briefly describe the organization in terms of its history and its present operations. Cite significant aspects of its current financial, general management, and health services delivery activities. Please include the following:

- A. The extent of the current Medicare population served by the Applicant, if any, and the maximum number of Medicare beneficiaries that could be served as a Direct Contract PDP.
- B. The manner in which benefits are currently provided to the current Medicare population served by the Applicant, if any, the number of beneficiaries in each employer sponsored group option currently made available by the Applicant and how these options are currently funded (self-funded or fully insured).

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- C. The current benefit design for each of the options described in B above, including premium contributions made by the employer and/or the retiree, deductible, co-payments, or co-insurance, etc. (Applicant may attach a summary plan description of its benefits or other relevant materials describing these benefits.)
- D. Information about other Medicare contracts held by the Applicant, (i.e., 1876, fee for service, PPO, etc.). Provide the names and contact information for all CMS personnel with whom Applicant works on their other Medicare contract(s).
- E. The factors that are most important to Applicant in considering to apply to become a Direct Contract PDP for its retirees and how becoming a Direct Contract PDP will benefit the Applicant and its retirees.

C. If the Applicant is a state agency, labor organization, or a trust established by one or more employers or labor organizations, Applicant must provide the required information listed below:

State Agencies:

If Applicant is a state agency, instrumentality or subdivision, please provide the relationship between the entity that is named as the Direct Contract PDP Applicant and the state or commonwealth with respect to which the Direct Contract PDP Applicant is an agency, instrumentality or subdivision. Also, Applicant must provide the source of Applicant's revenues, including whether applicant receives appropriations and/or has the authority to issue debt.

Labor Organizations:

If Applicant is a labor organization including a fund or trust, please provide the relationship (if any) between Applicant and any other related labor organizations such as regional, local or international unions, or welfare funds sponsored by such related labor organizations. If Applicant is a jointly trustee Taft-Hartley fund, please include the names and titles of labor-appointed and management-appointed trustees.

Trusts:

If Applicant is a trust, such as a voluntary employee beneficiary association under Section 501(c)(9) of the Internal Revenue Code, please provide the names of the individual trustees and the bank, trust company or other financial institution that has custody of Applicant's assets.

D. Policymaking Body (42 CFR 423.504(b)(4)(i)-(iii))

In general, an entity seeking to contract with CMS as a Direct Contract PDP Sponsor must have policymaking bodies exercising oversight and control to ensure actions are in the best interest of the organization and its enrollees, appropriate personnel and systems relating to medical services, administration and management, and an executive manager whose appointment and removal are under the control of the policymaking body.

An employer or union directly contracting with CMS as a Direct Contract PDP Sponsor may be subject to other, potentially different standards governing its management and

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operations, such as ERISA fiduciary requirements, state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. In most cases, they will also contract with outside vendors (i.e., business associates) to provide health benefit plan services. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers and unions from considering applying to offer Direct Contract PDPs, the management and operations requirements under 42 CFR 423.504(b)(4)(i)-(iii) are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for health benefit plan services) is subject to ERISA fiduciary requirements or similar state or federal laws and standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other PDP Sponsors. In accordance with the terms of this waiver, please provide the following information:

- A. List the members of the organization's policymaking body (name, position, address, telephone number, occupation, term of office and term expiration date). Indicate whether any of the members are employees of the Applicant.
- B. If the Applicant is a line of business versus a legal entity, does the Board of Directors of the corporation serve as the policymaking body of the organization? If not, describe the policymaking body and its relationship to the corporate Board.
- C. Does the Federal Government or a State regulate the composition of the policymaking body? If yes, please identify all Federal and State regulations that govern your policymaking body (e.g., ERISA).

II. FINANCIAL DOCUMENTATION

A. Minimum Net Worth: \$1.5 Million - Documentation of Minimum Net Worth

The Direct Contract PDP Applicant must demonstrate financial solvency through furnishing two years of independently audited financial statements to CMS. If the Direct Contract PDP Applicant has not been in operation at least twelve months, it may choose to: 1) obtain independently audited financial statements for a shorter time period; or 2) demonstrate that it has the minimum net worth through presentation of un-audited financial statements that contain sufficient detail to allow CMS to verify the validity of the financial presentation. The un-audited financial statement must be accompanied by an actuarial opinion from a qualified actuary regarding the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.

A "qualified actuary" for purposes of this application means a member in good standing of the American Academy of Actuaries, a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial science and is satisfactory to CMS.

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If the Direct Contract PDP Applicant's auditor is not one of the 10 largest national accounting firms in accordance with the list of the 100 largest public accounting firms published by the CCH Public Accounting Report, the Applicant should enclose proof of the auditor's good standing from the relevant state board of accountancy.

B. Liquidity

The Direct Contract PDP Applicant must have sufficient cash flow to meet its financial obligations as they become due. The amount of the minimum net worth requirement to be met by cash or cash equivalents is \$750,000. Cash equivalents are short-term highly liquid investments that can be readily converted to cash. To be classified as cash equivalents, investments must have a maturity date not longer than 3 months from the date of purchase.

In determining the ability of a Direct Contract PDP Applicant to meet this requirement, CMS will consider the following:

1. The timeliness of payment,
2. The extent to which the current ratio is maintained at 1:1 or greater, or whether there is a change in the current ratio over a period of time; and
3. The availability of outside financial resources.

CMS may apply the following corresponding corrective remedies:

1. If a PDP Sponsor fails to pay obligations as they become due, CMS will require the PDP Sponsor to initiate corrective action to pay all overdue obligations.
2. CMS may require the PDP Sponsor to initiate corrective action if any of the following are evident:
 - a) The current ratio declines significantly; or
 - b) A continued downward trend in the current ratio. The corrective action may include a change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding to restore the current ratio to at least 1:1.
3. If there is a change in the availability of outside resources, CMS will require the PDP Sponsor to obtain funding from alternative financial resources.

C. Methods of Accounting

A Direct Contract PDP Applicant generally must use the standards of Generally Accepted Accounting Principles (GAAP). Generally Accepted Accounting Principles (GAAP) are those accounting principles or practices prescribed or permitted by the Financial Accounting Standards Board. However, a Direct Contract PDP Sponsor whose audited financial statements are prepared using accounting principles or practices other than GAAP, such as a governmental entity that reports in accordance with the principles promulgated by the Governmental Accounting Standards Board (GASB), may utilize such alternative standard.

D. Bonding and Insurance

A Direct Contract PDP Applicant may request a waiver in writing of the bonding and/or insurance requirements set forth at 42 CFR 423.504(b)(4)(iv) and (v). Relevant considerations will include demonstration that either or both of the foregoing requirements are unnecessary based on the entity's individualized circumstances, including maintenance of similar coverage pursuant to other law, such as the bonding requirement at ERISA Section 412.

E. Additional Information

A Direct Contract PDP Applicant must furnish the following financial information to CMS to the extent applicable:

1. **Self-Insurance/Self Funding:** If the Direct Contract PDP Applicant's health plan(s) are self-insured or self-funded, it must forward proof of stop-loss coverage (if any) through copies of policy declarations.
2. **Trust:** If the Direct Contract PDP Applicant maintains one or more trusts with respect to its health plan(s), a copy of the trust documents, and if the trust is intended to meet the requirements of Section 501(c)(9) of the Internal Revenue Code, the most recent IRS approval letter.
3. **Forms 5500 and M-1:** The two most recent annual reports on Forms 5500 and M-1 (to the extent applicable) for the Direct Contract PDP Applicant's health plans that cover prescription drugs for retirees that are Part D eligible individuals.
4. **ERISA Section 411(a) Attestation:** Each applicant (including an applicant that is exempt from ERISA) must provide a signed attestation that no person serves as a fiduciary, administrator, trustee, custodian, counsel, agent, employee, consultant, adviser or in any capacity that involves decision-making authority, custody, or control of the assets or property of any employee benefit plan sponsored by the Direct Contract PDP Applicant if he or she has been convicted of, or has been imprisoned as a result of his or her conviction of, one of the felonies set forth in ERISA Section 411(a), for 13 years after such conviction or imprisonment (whichever is later).
5. **Defined Benefit Pension Plan:** If the Direct Contract PDP Applicant sponsors one or more defined benefit pension plans (within the meaning of ERISA Section 3(35)) that is subject to the requirements of Title IV of ERISA, the latest actuarial report for each such plan.
6. **Multi-Employer Pension Plan:** If the Direct Contract PDP Applicant is a contributing employer with respect to one or more multi-employer pension plans within the meaning of ERISA Section 3(37), the latest estimate of contingent withdrawal liability.
7. **Tax-Exempt Applicants Only:** A copy of the most recent IRS tax-exemption.

III. INSOLVENCY REQUIREMENTS

A. Hold Harmless and Continuation of Coverage/Benefits

A Direct Contract PDP Applicant shall be subject to the same hold harmless and continuation of coverage/benefit requirements as Medicare Advantage contractors.

B. Insolvency Deposit

A Direct Contract PDP Applicant generally must forward confirmation of its establishment and maintenance of an insolvency deposit of at least \$100,000, to be held in accordance with CMS requirements by a qualified U. S. Financial Institution. A “qualified financial institution” means an institution that:

1. Is organized or (in the case of a U.S. office of a foreign banking organization) licensed under the laws of the United States or any state thereof; and
2. Is regulated, supervised, and examined by the U.S. Federal or State authorities having regulatory authority over banks and trust companies.

A Direct Contract PDP Applicant may request a waiver in writing of this requirement.

IV. GUARANTEES (only applies to an Applicant that utilizes a Guarantor)

A. General Policy

A Direct Contract PDP Applicant, or the legal entity of which the Direct Contract PDP Applicant is a component, may apply to CMS to use the financial resources of a Guarantor for the purpose of meeting the requirements of a Direct Contract PDP Applicant set forth above. CMS has the sole discretion to approve or deny the use of a Guarantor.

B. Request to Use a Guarantor

To apply to use the financial resources of a Guarantor, a Direct Contract PDP Applicant must submit to CMS:

1. Documentation that the Guarantor meets the requirements for a Guarantor under paragraph (C) of this section; and
2. The Guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the Guarantor's balance sheets, profit and loss statements, and cash flow statements.

C. Requirements for Guarantor

To serve as a Guarantor, an organization must meet the following requirements:

1. Is a legal entity authorized to conduct business within a State of the United States.

2. Not be under Federal or State bankruptcy or rehabilitation proceedings.
3. Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PDP Sponsor guarantee.
4. If a State insurance commissioner or other State official with authority for risk-bearing entities regulates the Guarantor, it must meet the net worth requirement in Section II.A above with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.
5. If the Guarantor is not regulated by a State insurance commissioner or other similar State official, it must meet the net worth requirement in Section II.A above with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

D. Guarantee Document

If the guarantee request is approved, a Direct Contract PDP Applicant must submit to CMS a written guarantee document signed by an appropriate Guarantor. The guarantee document must:

1. State the financial obligation covered by the guarantee;
2. Agree to:
 - a) Unconditionally fulfill the financial obligation covered by the guarantee; and
 - b) Not subordinate the guarantee to any other claim on the resources of the Guarantor;
3. Declare that the Guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and
4. Meet any other conditions as CMS may establish from time to time.

E. Ongoing Guarantee Reporting Requirements

A Direct Contract PDP Sponsor must submit to CMS the current internal financial statements and annual audited financial statements of the Guarantor according to the schedule, manner, and form that CMS requires.

F. Modification, Substitution, and Termination of a Guarantee

A Direct Contract PDP Sponsor cannot modify, substitute or terminate a guarantee unless the Direct Contract PDP Sponsor:

1. Requests CMS's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;
2. Demonstrates to CMS's satisfaction that the modification, substitution, or termination will not result in insolvency of the Direct Contract PDP Applicant; and
3. Demonstrates how the Direct Contract PDP Applicant will meet the requirements of this section.

G. Nullification

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If at any time the Guarantor or the guarantee ceases to meet the requirements of this section, CMS will notify the Direct Contract PDP Sponsor that it ceases to recognize the guarantee document. In the event of this nullification, a Direct Contract PDP Sponsor must:

1. Meet the applicable requirements of this section within 15 business days; and
2. If required by CMS, meet a portion of the applicable requirements in less than the 15 business days in paragraph (G.1.) of this section.

V. ONGOING REPORTING REQUIREMENTS

An approved Direct Contract PDP Applicant is required to update financial information set forth in Sections II and III above to CMS on an ongoing basis. The schedule, manner, and form of reporting will be in accordance with CMS requirements.

Appendix II

Direct Contract PDP Attestations For Contract _____

1. SERVICE AREA & PHARMACY ACCESS REQUIREMENTS

In general, Part D plans can only cover beneficiaries in the service areas in which they are licensed and approved by CMS to offer benefits. CMS has waived this requirement for Direct Contract PDP Sponsors. Direct Contract PDP Sponsors can extend coverage to all of their retirees, regardless of whether they reside in one or more other PDP regions in the nation. In order to provide coverage to retirees wherever they reside, Direct Contract PDP Sponsors must set their service areas to include all areas where retirees may reside during the plan year (**no mid-year service area expansions will be permitted**). Applicants will be required to submit retail and other pharmacy access information (mail order, home infusion, long-term care, I/T/U) for the entire defined service area during the application process and demonstrate sufficient access in these areas in accordance with employer group waiver pharmacy access policy.

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract PDP. I have read, understand, and agree to comply with the above statement about service areas and pharmacy access. If I need further information, I will contact one of the individuals listed in the instructions for this application.

{Entity **MUST** complete for a complete application.}

2. CERTIFICATION

All provisions of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* apply to all plan benefit packages offered by PDP Sponsor except where the provisions are specifically modified and/or superseded by particular employer/union-only group waiver guidance, including those waivers/modifications set forth below (specific sections of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* that have been waived or modified for new PDP Sponsor Applicants are noted in parentheses).

I, the undersigned, certify to the following:

1) Applicant is applying to offer new employer/union Direct Contract prescription drug plans (PDPs) and agrees to be subject to and comply with all CMS employer/union-only group waiver guidance.

2) Applicant understands and agrees that it must complete and submit the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* in addition to this *2010 Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plan (PDP) Sponsors* in its entirety. The *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* along with Appendix I (Part D Financial Solvency & Capital Adequacy Documentation) and Appendix III (Request For Additional Waiver/Modification of Requirements (Optional)) of the *2010 Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plan (PDP) Sponsors* and this attestation (Appendix II) comprise a new Direct Contract PDP Sponsor Applicant's entire application.

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3) A Part D Sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers its coverage (42 CFR 423.504(b)(2)). However, CMS has waived the state licensing requirement for all Direct Contract PDP Sponsors along with the requirement to be a nongovernmental legal entity (42 CFR 423.4). As a condition of this waiver, Applicant understands that CMS will require such entities to meet the financial solvency and capital adequacy standards contained in Appendix I of this application. (Sections 3.1.1.A.1 and 3.1.3 of the *2009 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

4) Applicant understands and agrees that it is not required to submit a 2010 Part D bid (i.e., bid pricing tool) to offer its Direct Contract PDP. (Section 3.2.6.A.1 of the *2010 Solicitation for Applications for New Prescription Drug Plan Plans (PDP) Sponsors*)

5) Applicant agrees to restrict enrollment in its Direct Contract PDP to those Part D eligible individuals eligible for the Direct Contract PDP's employment-based retiree prescription drug coverage. Applicant agrees not to enroll active employees into its Direct Contract PDP. (Sections 3.5.A.3 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

6) In order to be eligible for the CMS retail pharmacy access waiver of 42 CFR 423.120(a)(1) (i.e., application of "TRICARE" standards), Applicant attests that its retail pharmacy network is sufficient to meet the needs of its enrollees throughout the Direct Contract PDP's service area, including situations involving emergency access, as determined by CMS. Applicant acknowledges and understands that CMS may review the adequacy of the plan's pharmacy networks and potentially require expanded access in the event of beneficiary complaints or for other reasons it determines in order to ensure that the plan's network is sufficient to meet the needs of its employer group population. (Section 3.4.1.A.1 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

7) Applicant understands and agrees that as part of its completion of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, it will submit GeoNetworks® retail pharmacy reports (Appendix X - Retail Pharmacy Network Access Instructions) and other pharmacy access submissions (mail order, home infusion, long-term care, I/T/U) required at the time of application in Section 3.4 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors* for its entire designated service area. (Sections 3.3.B and 3.4 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

8) Applicant understands that its Direct Contract PDP will not be included in the processes for auto-enrollment (for full-dual eligible beneficiaries) or facilitated enrollment (for other low income subsidy eligible beneficiaries). (Sections 3.2.6.A.2 and 3.5.A.4 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

9) Applicant understands that CMS has waived the requirement that the Direct Contract PDP must provide beneficiaries the option to pay their premium through Social Security withholding. Thus, the premium withhold option will not be available for enrollees in Applicant's Direct Contract PDP. (Sections 3.5.A.19 and 3.22.A.2-4 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

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10) Applicant understands that dissemination materials for its Direct Contract PDP are not subject to the requirements contained in 42 CFR 423.50 to be submitted for review and approval by CMS prior to use. However, Applicant agrees that it will submit these materials to CMS at the time of use in accordance with the procedures outlined in Chapter 12 of the Prescription Drug Benefit Manual. Applicant also understands that CMS reserves the right to review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. (Section 3.13.A.1 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

11) Applicant understands that its Direct Contract PDP will not be subject to the requirements regarding the timing for issuance of certain dissemination materials, such as the Annual Notice of Change/ Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), Formulary, and LIS rider when an employer's or union's open enrollment period does not correspond to Medicare's Annual Coordinated Election Period. For these employers and unions, the timing for issuance of the above dissemination materials should be appropriately based on the employer/union sponsor's open enrollment period. For example, the Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Summary of Benefits (SB), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the employer/union group health plan's open enrollment period. The timing for other dissemination materials that are based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor's plan year. (Section 3.13.A.10 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

12) Applicant understands that the dissemination requirements set forth in 42 CFR 423.128 will not apply to its Direct Contract PDP when the employer/union sponsor is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and complies with such alternative requirements. Applicant agrees to comply with the requirements for this waiver contained in employer/union-only group waiver guidance, including those requirements contained in Chapter 12 of the Prescription Drug Benefit Manual. (Sections 3.13.A.1-2, 8 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

13) Applicant understands that its Direct Contract PDP will not be subject to the requirements contained in 42 CFR 423.48 to submit information to CMS, including the requirements to submit information (e.g., pricing and pharmacy network information) to be publicly reported on www.medicare.gov and the Medicare Prescription Drug Plan Finder. (Sections 3.7.A.1-3 and 3.16.A.20 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

14) Applicant understands that its Direct Contract PDP will not be subject to the Part D beneficiary customer service call center hours and call center performance requirements. Applicant attests that it will ensure that a sufficient mechanism is available to respond to beneficiary inquiries and will provide customer service call center services to these members during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other

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reasons in order to ensure that the entity's customer service call center hours are sufficient to meet the needs of its enrollee population. (Section 3.13.A.5 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

15) Applicant understands that the management and operations requirements of 42 CFR 423.504(b)(4)(i)-(iii) are waived if the employer or union (or to the extent applicable, the business associate with which it contracts for prescription drug benefit services) is subject to ERISA fiduciary requirements or similar state or federal law standards. However, Applicant understands that it (or its business associates) are not relieved from the record retention standards applicable to other Part D Sponsors set forth in 42 CFR 423.505(d). (Section 3.1.1.A.2-4 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

16) In general, Part D plan Sponsors must report certain information to CMS, to their enrollees, and to the general public (such as the cost of their operations and financial statements) under 42 CFR 423.514(a). Applicant understands that in order to avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer sponsored group plans, CMS will modify these reporting requirements for Direct Contract PDPs to allow information to be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract. (Section 3.16.A.18-19 of the *2010 Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*)

17) This Certification is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations and policies implementing or interpreting such statutory provisions.

18) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS immediately and in writing.

19) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.

20) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

21) I acknowledge that I am aware that there is operational policy guidance, including the forthcoming 2010 Call Letter, relevant to this application that is posted on the CMS website and that it is continually updated. Organizations submitting an application in response to this solicitation acknowledge that they will comply with such guidance should they be approved to offer employer/union-only group waiver plans in association with the organization's PDP Contract with CMS.

Employer/Union Direct Contract PDP

I certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to offer employer/union-only Direct Contract plans in association with my organization's PDP Contract with CMS. I have read and agree to comply with the above certifications.

{Entity MUST check box for a complete application.}

Appendix III (Optional)

REQUEST FOR ADDITIONAL WAIVER/MODIFICATION OF REQUIREMENTS:

As a part of the application process, Applicants may submit individual waiver/modification requests to CMS. The Applicant should submit these additional waiver/modifications via an upload in HPMS to the Attestation Waiver Request field of the Part D supporting files.

These requests must be identified as requests for additional waivers/modifications and must fully address the following items:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the entity is requesting to be waived/modified (please identify the specific requirement (e.g., 42 CFR 423.32, Section 30.4 of the Part D Enrollment Manual) and whether you are requesting a waiver or a modification of these requirements);
- How the particular requirements hinder the design of, the offering of, or the enrollment in, the employer-sponsored group prescription drug plan;
- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group prescription drug plan;
- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and
- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.

ASSISTANCE:

If you have any questions about this application, please contact:

Marla Rothouse by email at Marla.Rothouse@cms.hhs.gov or by phone at 410-786-8063 or Linda Anders by email at Linda.Anders@cms.hhs.gov or by phone at 410-786-0459.